510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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Date Prepared: March 22, 2012

B. Device Name

Trade or Proprietary Name:	*NuVasive® NVJJB System*
Common or Usual Name:	Neurological surgical monitor
Classification Name:	Surgical Nerve Stimulator/Locator
Device Class:	Class II
Regulation:	§874.1820
Product Code:	ETN, GWF, IKN

C. Predicate Devices

The subject *NuVasive® NVJJB System* is substantially equivalent to one or more of the following predicate devices listed in **Table 1** below.

510(k)	Trade or proprietary or model name	Manufacturer
K112718	NVM5® System	NuVasive, Inc.
K061113	NIM Eclipse and probes (formerly Axon Systems OrthoMon System)	Medtronic Xomed, Inc.
K051357	DS7A Constant Current High Voltage Stimulator	Digitimer LTD
K061148	Disc Electrodes	Rhythmlink International, LLC
K022914	Subdermal Needle Electrodes	Rhythmlink International, LLC
K112709	Stimulation/Dissection Instruments	NuVasive, Inc.

D. Device Description

The *NVJJB® System* is a medical device that is intended for intraoperative neurophysiological monitoring and status assessment during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiological status. *NVJJB* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG) or transcranial motor evoked potential (TceMEP) responses of the muscle groups innervated by the nerves. Moreover, a Twitch Test ("Train of Four") function is utilized to test the ability of the nerve to respond, or contract, following four stimulation pulses to determine the presence of neuromuscular block.

Additionally, the *NVJJB System* also offers an optional screen sharing application (*Remote Monitoring*) to allow a secondary physician to remotely view the events represented on the NVJJB user interface. In summary, the *NVJJB System* includes the following three (3) software functionalities / modalities:

1. Electromyography (EMG)
2. Transcranial Motor Evoked Potential (TceMEP), or simply MEP
3. Remote Monitoring

The *NVJJB® System* hardware consists of a Patient Module (PM) and a Control Unit (CU) comprised of an embedded computer with touch screen controls and an interface card, as well as accompanying accessory components which consist of an assortment of disposable conductive probes, electrodes, and electrode leads

E. Intended Use

The *NVJJB® System* is a medical device that is intended for intraoperative neurophysiological monitoring and status assessment during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiological status. *NVJJB®* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG) or transcranial motor evoked potential (TcMEP) responses of nerves.

- MaXcess Detection – The MaXcess Detection function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool.
- Difference Screw Test (DST) – The DST function allows the surgeon to locate and evaluate spinal nerves before, during, or after placement of bone screws by verifying nerve integrity and factoring it into the alarm criteria.
- Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws.
- Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.

- Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses.
- TcMEP – Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract. The TcMEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury.
- Remote Reader – The Remote Reader function provides real time remote access to the NVJJB System for a monitoring physician outside of the operating room.
- Nerve Retractor – The Nerve Retractor function allows the surgeon to locate and identify spinal nerves by directly stimulating exposed nerves to assist in identifying neurophysiological changes during retraction.

F. Technological Characteristics

As was established in this submission, the subject *NVJJB® System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and functions.

Comparison of Technical Characteristics

Specification/ Property	Subject Device	Predicate Devices		
	NuVasive NVJJB System (K112717)	**NuVasive NVM5 System (K112718)**	**Medtronic NIM Eclipse (K061113)**	**MEPS, LLC. Digitimer (K051357)**
Intended Use/ Indications for Use	The *NVJJB® System* is a medical device that is intended for intraoperative neurophysiological monitoring and status assessment during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiological status. *NVJJB®* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG) or transcranial motor evoked potential (TcMEP) responses of nerves. • MaXcess Detection – The MaXcess Detection function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool. • Difference Screw Test (DST) – The DST function allows the surgeon to locate and evaluate spinal nerves before, during, or after placement of bone screws by verifying nerve integrity and factoring it into the alarm criteria. • Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws. • Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions. • Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses. • TcMEP – Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract. The TcMEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury. • Remote Reader – The Remote Reader function provides real time remote access to the NVJJB System for a monitoring physician outside of the operating room. • Nerve Retractor – The Nerve Retractor function allows the surgeon to locate and identify spinal nerves by directly stimulating exposed nerves to assist in identifying neurophysiological changes during retraction.	The *NVM5® System* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. *NVM5®* provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial motor evoked potential (TcMEP) or somatosensory evoked potential (SSEP) responses of nerves. • XLIF (Detection) – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool. • Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws. • Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions. • Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses. • TcMEP – Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract. The TcMEP function provides an adjunctive method to allow the surgeon to monitor spinal cord motor pathway integrity during procedures with a risk of surgically induced motor injury. • SSEP – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk. • Remote Reader – The Remote Reader function provides real time remote access to the NVM5 System for a monitoring physician outside of the operating room. • The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar spine of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.	The OrthoMon system is intended for use to record, monitor and stimulate/record biopotential signals including electromyography (EMG), evoked response and nerve/muscle potentials and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at risk nerve roots	The DS7A and DS7AH are stimulators intended for use during neurological monitoring and assessment in a clinical environment. They are intended for use by trained personnel either competent to apply appropriate stimuli or under the supervision and instruction of one who is.

Specification/ Property	Subject Device	Predicate Devices		
	NuVasive NVJJB System (K112717)	NuVasive NVM5 System (K112718)	Medtronic NIM Eclipse (K061113)	MEPS, LLC. Digitimer (K051357)
Total Available Channels	8	32	32	2 Stimulation
Headbox/ Patient Module	Digital Preamplifier with A/D Converter	Yes	Yes	None
IEC 60601-1 Compliant	Yes	Yes	Yes	Yes
Full Scale View Range	± 0.5µV to ± 8mV	± 0.5µV to ± 8mV	±10 µV to ±25mv	N/A-Stimulation Only
Frequency Response	30 Hz to 4.8 kHz	3 Hz to 4.8 kHz	1Hz to 4 kHz	N/A-Stimulation Only
User Interface	Touch screen and [optional] keyboard/mouse	Touch screen and [optional] keyboard/mouse	Touch screen and keyboard/mouse	Push button, Dials, Switches and LCD numbers
Remote Monitoring	Yes	Yes	Yes	N/A-MEP only
Train of Four Testing	Various	Yes	Yes	N/A-MEP only
Needle Electrodes	Various	Various	Various	N/A-MEP only
Surface Electrodes	Various	Various	Various	N/A-MEP only
Electrode Leads	Various	Various	Various	N/A-MEP only
Stimulating Probes	Various	Various	Various	N/A-MEP only
Recording Channels	8	EMG, MEP, and SSEP	EMG, MEP, and SSEP	No
EMG				
Number of Recording Channels	8	10	32	N/A
Response Threshold	10-300µV user settable for free run and stimulated	10-300 µV	10 µV to 10 mV	N/A
High Filter	1.5k Hz	1.5 kHz	10 kHz	N/A
Low Filter	30 Hz	0.030 kHz	0.5 kHz	N/A
Notch Filter	None	None	50 or 60 Hz	N/A
Audible EMG	Yes	Yes	Yes	N/A

Specification/ Property	Subject Device	Predicate Devices		
	NuVasive NVJJB System (K112717)	**NuVasive NVM5 System (K112718)**	**Medtronic NIM Eclipse (K061113)**	**MEPS, LLC. Digitimer (K051357)**
CMRR	> 100 dB	> 100 dB @ 60 Hz	> 100 dB @ 60 Hz	N/A
A/D Sampling Rate	9.6 kHz	9.6 kHz	Unknown	N/A
Automatic Muting During Artifact	Yes	Yes	Yes	N/A
Stimulation Waveform	Rectangular, Monophasic Pulse	Rectangular, Monophasic Pulse	Rectangular, Monophasic and Biphasic Pulse	N/A
Constant Current/ Voltage	Yes	Yes	Yes	N/A
Theoretical Max Voltage	240 V	300 V	400 V	N/A
Max Current	0.05 A	0.09 A	0.1 A	N/A
Max Pulse Width	0.0002 sec	0.0002 sec	0.0005 sec	N/A
Max Number of Pulses per second	5	5	100	N/A
Min Probe Surface Area	0.169 cm^2	0.169 cm^2	0.002 cm^2	N/A
Calculated Values per IEC 60601-2-40				
Voltage	50 V	90 V	100 V	N/A
Max RMS Current	1.6 mA_{RMS}	2.8 mA_{RMS}	22.3 mA_{RMS}	N/A
Max RMS Current Density	6.1 mA_{RMS}/cm^2	16.57 mA_{RMS}/cm^2	11,150 mA_{RMS}/cm^2	N/A
Max Charge Density	59 $\mu C/cm^2$	107 $\mu C/cm^2$	25,000 $\mu C/cm^2$	N/A
Max Power Density	15 W/cm^2	48 W/cm^2	5000 W/cm^2	N/A

Specification/ Property	Subject Device	Predicate Devices		
	NuVasive NVJJB System (K112717)	NuVasive NVM5 System (K112718)	Medtronic NIM Eclipse (K061113)	MEPS, LLC. Digitimer (K051357)
MEP				
Theoretical Max Voltage	1000 V	1000 V	N/A	1000 V
Max Current	1.0 A	1.0 A	N/A	1.0 A
Max Pulse Width	0.00005 sec	0.00005 sec	N/A	0.00005 sec
Max Number of Pulses per second	4	8	N/A	10
Min Surface Area Electrode	0.492 cm^2	0.492 cm^2	N/A	0.492 cm^2
Calculated Values per IEC 60601-2-40				
Max Energy	50 mJ	50 mJ	N/A	50 mJ
Voltage	1000 V	1000 V	N/A	1000 V
Max RMS Current	14 mA_{RMS}	20 mA_{RMS}	N/A	22 mA_{RMS}
Max RMS Current Density	28.4 mA_{RMS}/cm^2	40.65 mA_{RMS}/cm^2	N/A	44.7 mA_{RMS}/cm^2
Max Charge Density	101 $\mu C/cm^2$	102 $\mu C/cm^2$	N/A	102 $\mu C/cm^2$
Max Power Density	2032 W/cm^2	2032 W/cm^2	N/A	2032 W/cm^2

Comparison of Electrode Technical Characteristics

	Subject NVJJB Dual Surface (K112717)	**Predicate Sticky pad™ Electrodes (K061148)**	**Subject NVJJB Dual Needle (K112718)**	**Predicate Subdermal Needle Electrodes (K050194)**	**Subject NVJJB Corkscrew (K112718)**	**Predicate Subdermal Needle Electrodes (K050194)**	**Subject NVJJB Cranial Array (K112718)**	**Predicate Subdermal Needle Electrodes (K061148)**
Manufacturer	NuVasive, Inc.	Rhythmlink International, LLC	NuVasive, Inc.	Rhythmlink International, LLC	NuVasive, Inc.	Rhythmlink International, LLC	NuVasive, Inc.	Rhythmlink International, LLC
Length(s)	N/A	N/A	Needle length: 12mm	Needle length: 13mm	N/A	N/A	Needle length: 12mm	Needle length: 13mm
Size(s)	Pad size: 17.81cm^2	Pad size: Min: 1.5 x 2.0cm (3.0cm^2) Max: 4.5 x 3.5cm (15.75cm^2)	Needle diameter: 0.036cm	Needle diameter: 0.04cm	Needle Diameter: 0.058cm Needle height: 0.302cm	Needle diameter: 0.06cm Needle height: 0.380cm	Needle diameter: 0.036cm	Needle diameter: 0.04cm
Stim/Record Surface Area	1.78cm^2	3 – 15.75cm^2	0.262cm^2	0.326cm^2	0.492cm^2	0.584cm^2	0.655cm^2	0.163cm^2

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NVJJB® System* is substantially equivalent to other predicate devices and to verify that the *NVJJB® System* meets design specifications and performance characteristics, based upon the intended use. The *NVJJB® System* was subjected to electrical safety and compatibility testing and was certified to the following standards, including all applicable normative reference standards:

- IEC 60601-1 (1988), A1 (1991), A2 (1995): Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-2-40 (1988): Medical Electrical Equipment Part 2-40:Particular requirements for the safety of electromyographs and evoked response equipment
- IEC 60601-1-2 (2001), A1 (2004): Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard Electromagnetic Compatibility

Accessories to the *NVJJB® System* also underwent the following performance testing, where applicable:

- Impedance and continuity testing
- Current density testing
- Electrical performance and durability
- Fluid interference
- Biocompatibility testing per ISO 10993-1
- Sterilization validation per ISO 11135-1
- Penetration and friction testing of needle electrodes

The results of these studies showed that the subject *NVJJB® System* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NVJJB® System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Incorporated
% Mr. Elias Ketchum
Senior Associate, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

APR 13 2012

Re: K112717
Trade/Device Name: NuVasive NVJJB System
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN, GWF, IKN
Dated: March 22, 2012
Received: March 26, 2012

Dear Mr. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112717

Device Name: *NuVasive® NVJJB® System*

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

John Grimes, Ph.D. Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112717